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10/618,133	07/11/2003	Lixiong Li	ARA-US-P1	4427
44702	7590	02/22/2006	EXAMINER	
OSTRAGER CHONG FLAHERTY & BROITMAN PC 250 PARK AVENUE, SUITE 825 NEW YORK, NY 10177			SAVAGE, MATTHEW O	
			ART UNIT	PAPER NUMBER
			1724	
DATE MAILED: 02/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/618,133

Applicant(s)

LI ET AL.

Examiner

Matthew O. Savage

Art Unit

1724

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 and 73-79 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,14,15,20,31,36,39-53,73-75 and 77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-13,16-19,21,22,32-35,37,38,76,78 and 79 is/are rejected.
- 7) ☒ Claim(s) 24-30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

New claims 74, 75, and 77 are directed to species of sensor arrangements not shown in any of the drawing Figures and have been withdrawn from consideration as being directed to non-elected inventions.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the spring-loaded adjustable pressure relief valve recited in claim 12 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed On 12-7-05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the original specification fails to have basis for a pressure relief valve having a single inlet and a single outlet as shown in proposed amended FIG. 3.

Applicant is required to cancel the new matter in the reply to this Office Action.

The proposed amendment to FIG. 3 concerning the pressure relief valve filed on 12-7-05 has not been approved by the examiner for the reasons set forth above.

The proposed amendment to FIG. 3 filed on 12-7-05 out-lining the process control system 22 has been approved by the examiner.

The proposed amendments to FIGS. 10A, 10B, 11A filed on 12-7-05 have been approved by the examiner.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 17 and 18, it is unclear as to what structure the “means for controlling the temperature of the fluid in the processor assembly” comprises phrase is does not appear in the instant specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10-13, 16, 78, and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2,002,736 to Alhauser.

With respect to claim 1, Alhouser discloses a pump 18 for drawing a fluid from a fluid source 10 through a fluid inlet 44 and pressurizing the fluid; a processor assembly 56 for processing the fluid from the pump; a process control system including a flow splitter 24 disposed between the pump 18 and the processor assembly 56 for diverting a portion of the fluid from the pump, a first flow restrictor 38 for receiving the diverted fluid and directing the diverted fluid to the fluid inlet, a pressure relief valve 36 disposed between the first flow restrictor and the flow splitter, and a second flow restrictor 64 disposed downstream of the processor assembly 56, the flow splitter, first flow restrictor, second flow restrictor and pressure relief valve being constructed and arranged to co-act with each other to be capable of controlling the pressure and flow rate of the fluid in the fluid processor.

Concerning claim 2, Alhauser disclose the process control system as maintaining the pressure of the fluid in the processor assembly at least about the saturation point of the fluid at a predetermined temperature (e.g., assumed to be ambient temperature).

Regarding claim 3, Alhauser disclose the flow splitter 24 is as being a filtration device (e.g., a reverse osmosis filter)

As to claim 4, Alhauser disclose the flow splitter 24 as being a reverse osmosis device.

Regarding claim 10, Alhauser discloses a check valve 16 disposed upstream of the fluid processor 24.

Concerning claim 11, Alhauser discloses a prefilter 14 disposed upstream of the processor assembly 24.

As to claim 12, Alhauser discloses a reverse osmosis device 24 downstream of the prefilter 14.

Regarding claim 13, Alhauser disclose a reverse osmosis device 24 and ion exchange device 48 between the prefilter 14 and processor 56.

Concerning claim 16, Alhauser discloses a processor 56 capable of processing water to produce sterile water for injection (see lines 5-10 of page 1).

With respect to claim 78, Alhouser discloses a pump 18 for drawing a fluid from a fluid source 10 through a fluid inlet 44 and pressurizing the fluid; a processor assembly 56 for processing the fluid from the pump; a process control system including a flow splitter 24 disposed between the pump 18 and the processor assembly 56 for diverting a portion of the fluid from the pump, a first flow restrictor 38 for receiving the diverted

Art Unit: 1724

fluid and directing the diverted fluid to the fluid inlet, a pressure relief valve 36 disposed between the first flow restrictor and the flow splitter, and, a second pressure relief valve 72 disposed between the processor assembly and the flow splitter, and a second flow restrictor 64 disposed downstream of the processor assembly, the flow splitter, first flow restrictor, second flow restrictor and pressure relief valve being constructed and arranged to coact with each other to be capable of controlling the pressure and flow rate of the fluid in the fluid processor.

Concerning claim 79, Alhouser discloses a third pressure relief valve 66 disposed downstream of the second flow restrictor 64.

Claims 1-4, 10-13, 16, and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,072,610 to Gow et al.

With respect to claim 1, Gow et al disclose a pump 20 (see FIG. 1) for drawing a fluid from a fluid source 10 through a fluid inlet and pressurizing the fluid; a processor assembly 50 for processing the fluid from the pump; a process control system including a flow splitter 24 disposed between the pump 20 and the processor assembly 50 for diverting a portion of the fluid from the pump, a first flow restrictor 28 for receiving the diverted fluid and directing the diverted fluid to the fluid inlet, a pressure relief valve 30 disposed between the first flow restrictor and the flow splitter, and a second flow restrictor 60 disposed downstream of the processor assembly, the flow splitter, first flow restrictor, second flow restrictor and pressure relief valve being constructed and

arranged to coact with each other to be capable of controlling the pressure and flow rate of the fluid in the fluid processor.

Concerning claim 2, Gow et al disclose the process control system as maintaining the pressure of the fluid in the processor assembly at least about the saturation point of the fluid at a predetermined temperature (e.g., at a temperature of the main sterilizer).

Regarding claim 3, Gow et al disclose the flow splitter 24 is as being a filtration device (e.g., a reverse osmosis filter)

As to claim 4, Gow et al disclose the flow splitter 24 as being a reverse osmosis device.

Concerning claim 11, Gow et al disclose a prefilter 14 disposed upstream of the processor assembly 50.

As to claim 12, Gow et al disclose a reverse osmosis device 24 downstream of the prefilter 14.

Concerning claim 16, Gow et al disclose a processor 50 capable of processing water to produce sterile water for injection.

As to claim 23, Gow et al disclose a heat exchanger 56 for recovering thermal energy, a reactor (e.g., the parallel tube arrangement disposed within the main sterilizer 50), and a heater for heating the reactor (the heating element and bath disposed within the main sterilizer).



Concerning claim 76, Gow et al disclose a pressure sensor for measuring the pressure of the fluid upstream of the processor assembly (e.g., the means for measuring differential pressure across filter 42, see lines 25-27 of col. 4).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alhauser in view of Kasten.

Concerning claim 5, Alhauser fail to specify the flow restrictor 38 as being a fixed setting flow restrictor. Kasten discloses that it is known to control flow in a recycle path of a filtration system with a fixed setting flow restrictor 50. Kasten suggests that such an arrangement is simple and economical to construct. It would have been obvious to have modified the apparatus of Alhauser so as to have included a fixed setting flow restrictor as suggested by Kasten in order to provide a flow restrictor that was simple and economical to construct.

As to claim 6, Kasten discloses a fixed setting flow restrictor in the form of a fixed length capillary tube (see FIG. 1).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alhauser in view of Leek, Jr..

With respect to claim 9, Alhauser disclose an adjustable valve 30 but fail to specify the valve as being spring-loaded. Leek, Jr. discloses a spring-loaded valve 61' for a reverse osmosis membrane filter and teaches that such a valve can be used to allow water to escape from the filter housing of an reverse osmosis filter to wash the membrane. It would have been obvious to have modified the valve of Alhauser so as to have included a spring loaded valve as suggested by Leek, Jr. in order to permit water to escape from the housing of the reverse osmosis filter to wash the membrane.

Claims 32-35, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gow et al as applied to claim 23 above, and further in view of Fox.

With respect to claim 32, Gow et al fail to specify a tube-in-tube heat exchanger. Fox discloses a fluid heater including a tube in tube heat exchanger 31, 23 with process fluid (e.g., cooler fluid) flowing through the annular side and the product fluid (e.g., hotter fluid) flowing through the tube side and suggests that such a heater has a high heating efficiency. It would have been obvious to have modified heat exchanger of Gow et al so as to have included the tube-in-tube heat exchanger arrangement as suggested by Fox in order to improve the efficiency of the processor.

Concerning claim 33, Fox discloses a helical tube-in-tube heat exchanger.

As to claim 34, Fox discloses a reactor 16 and heater 17 disposed within the heat exchanger 31, 23.

Regarding claim 35, Fox discloses the reactor 16 and heater 17 as being disposed within a temperature homogenizer 5, 12, 15.

As to claim 37, Fox discloses the temperature homogenizer as including a unitary structure 12 or 15 produced by casting (see lines 65-66 and 76-78 of page 1), the reactor 16 being an integral part of the homogenizer.

Concerning claim 38, Fox discloses the temperature homogenizer as being enclosed by an insulation jacket 20.

Claims 17-19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gow et al as applied to claim 23 above, and further in view of Benedict.

Gow et al fail to specify the temperature sensor, temperature controller, touch screen interface, logic controller, pressure transducer, pump controller, endotoxin sensor and signal conditioner, and conductivity cell as recited in claims 17-19, however, Benedict discloses that the use of elements to automatically control and monitor a fluid treatment process is known in the art (see FIG. 1 and paragraphs 23 and 26). It would have been obvious to have modified the apparatus of Gow et al so as to have included the process control elements disclosed by Benedict in order to provide automatic control of the process and to enable monitoring of the process.

Concerning claims 21-22, Gow et al disclose a divert line 70 downstream of the processor 50. Benedict fail to specify placing the flow sensor, conductivity cell, and endotoxin sensor along a divert line, however, such a modification would have been

Art Unit: 1724

obvious in order to enable monitoring the quality of the finished product in the single pass treatment process of Gow et al.

Claim 78 would be allowable over the art of record if amended as follows.

78. A fluid process comprising

a pump for drawing a fluid from a fluid source through a fluid inlet and pressurizing the fluid;

a processor assembly including a fluid heater for ~~processing~~ heating the fluid from the pump; a process control system including a flow splitter disposed between the pump and the processor assembly for diverting a portion of the fluid from the pump, a first flow restrictor for receiving the diverted fluid and directing the diverted fluid to the fluid inlet, a pressure relief valve disposed between the first flow restrictor and the flow splitter, and, a second pressure relief valve disposed between an upstream side of the processor assembly and a downstream side of the flow splitter and a second flow restrictor disposed downstream of the processor assembly,

wherein the flow splitter, first flow restrictor, second flow restrictor and pressure relief valve being constructed and arranged to coact with each other to be capable of controlling the pressure and flow rate of the fluid in the fluid processor.

It is noted that Alhouser fails to teach or suggest the inclusion of a fluid heater as recited in proposed amended claim 78 and that Gow et al fail to teach

or suggest a second pressure relief valve as recited in proposed amended claim 78.

Claims 24-30 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed 12-7-06 have been fully considered but they are not persuasive.

The objection to the drawings has been maintained since an adjustable spring-loaded type pressure relief valve has not been shown in the drawings.

Applicant argues that Alhouser fails to specify a "processor assembly" as recited in claim 1, however, it is held that the term "processor assembly" is broad enough to be anticipated by the reverse osmosis membrane disclosed by Alhouser that processes a fluid by filtering.

Applicant argues that the throttle valve 36 disclosed by Alhouser cannot be considered a pressure relief valve, however, it is held that the valve 36 can function as a pressure relief valve since it removes excess fluid and pressure from the system.

Applicant argues that the flow splitter, first flow restrictor, second flow restrictor, and pressure relief valve of Alhouser are not constructed and arranged to control the pressure and flow rate of fluid in the system, however, it is held that the Alhouser elements are capable of such a functions since they constructed and arranged as recited in the body of instant claim 1.

Applicant argues that Alhouser fails to anticipate claim 2, however, the rejection is maintained since the material treated in the Alhouser system is water and is maintained in liquid form.

Applicant argues that the flow splitter of claim 1 cannot be considered a reverse osmosis membrane as recited in claims 12 and 13, however, the rejection is maintained since applicant's invention includes a flow splitter in the form of a reverse osmosis filter in the case of the elected species and because the claims do not expressly separate the elements.

Applicant argues that Gow et al fail to disclose a pressure relief valve disposed between a flow restrictor and a flow splitter as recited in claim 1, however, it is held that Gow et al clearly disclose a branch line and valve 30 capable of functioning as a pressure relief valve disposed between a flow restrictor 28 and a flow splitter 24.

Applicant argues that Gow et al fail to anticipate claim 2, however, the rejection is maintained since the treated liquid is an aqueous solution maintained in a liquid form while passing through the processor 50.

Applicant's argument that Kasten fails to specify a processor as recited in claims 5 and 6 is not agreed with since he clearly includes a processor in the form of a fluid filter. Applicant should note that Alhouser is relied upon as a disclosure of a processor in combination with a process control system.

Applicant argues that Leek fails to specify a spring loaded pressure relief valve as recited in claim 9, however, Leek clearly discloses such a valve (see line 13 of col. 5)

since it relieves liquid and excess pressure from the upstream/concentrate side of a reverse osmosis membrane.

Applicant argues that Fox fails to disclose a homogenizer as recited in claims 35 and 36, however, elements 5, 12, and 15 can be broadly construed as forming a homogenizer since they function to transfer heat from the heater to the liquid.

Applicant argues that Fox fails to include an insulation jacket as recited in claim 38, however, Fox clearly discloses an insulation jacket 20 that encloses the homogenizer.

Applicant's argument that Benedict fails to disclose the details of claim 1 is noted, however, such details are disclosed by Gow et al.

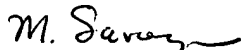
Applicant argues that Gow et al fail to specify a divert line, however, it is held that Gow et al disclose a line 70 that can be considered a divert line since it diverts the fluid from a filter to a bottling line.

Applicant argues that there is no motivation to combine Gow et al and Benedict, however, it is held that one skilled in the art would combine the references since they are both directed to liquid treatment systems.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew O. Savage whose telephone number is (571) 272-1146. The examiner can normally be reached on Monday-Friday, 7:00am-3:30pm.

  
Matthew O Savage  
Primary Examiner  
Art Unit 1724

mos  
February 20, 2006



ANNOTATED SHEET SHOWING CHANGES

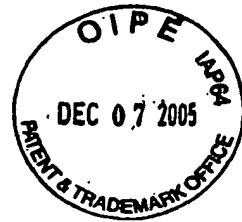
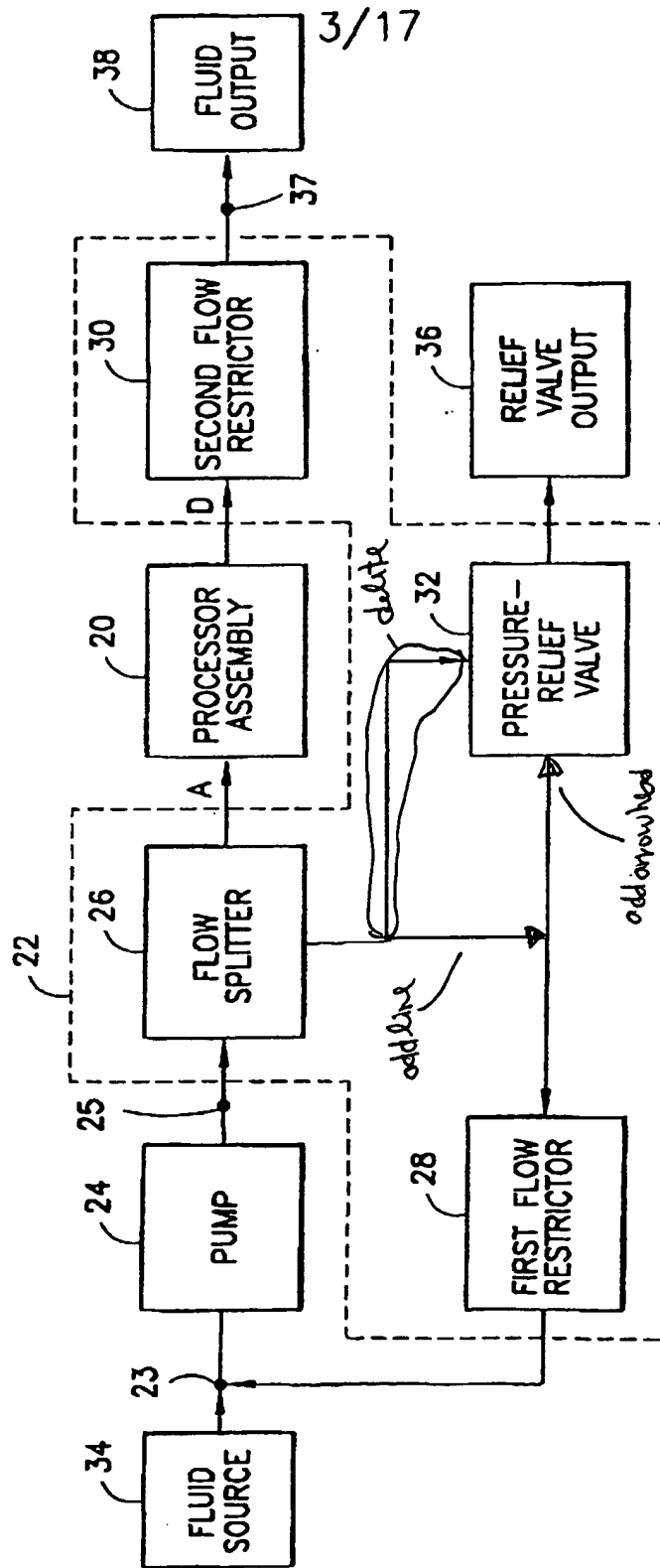


FIG. 3

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13/17

PROCESSOR ASSEMBLY

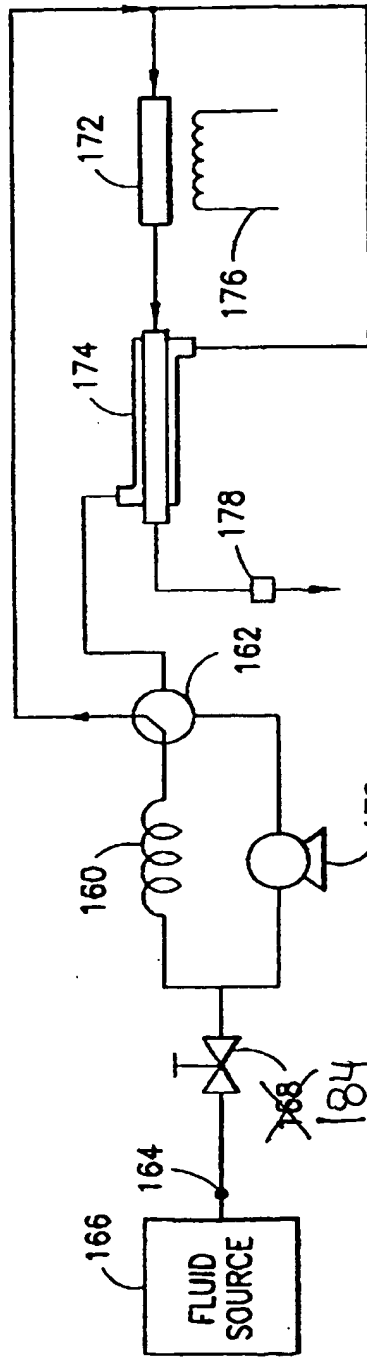


FIG. 10A

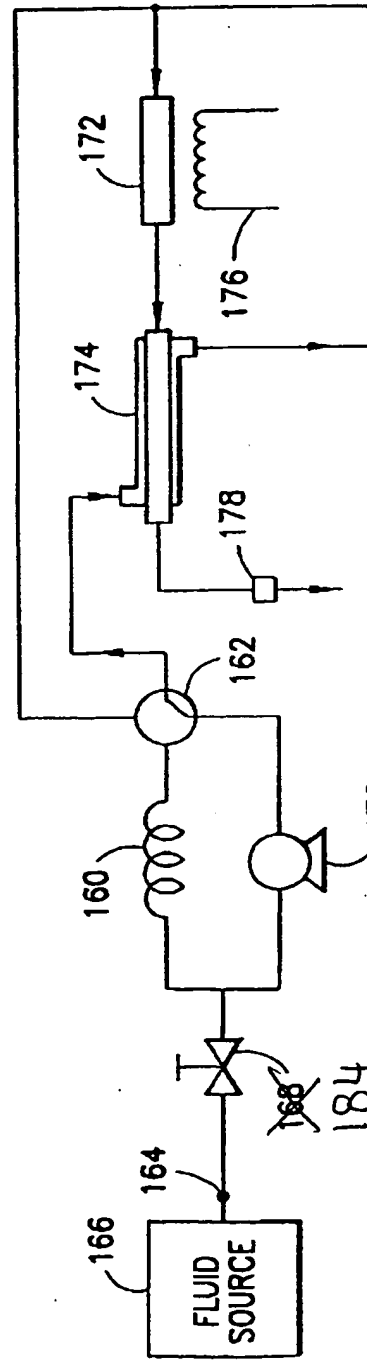


FIG. 10B

14/17

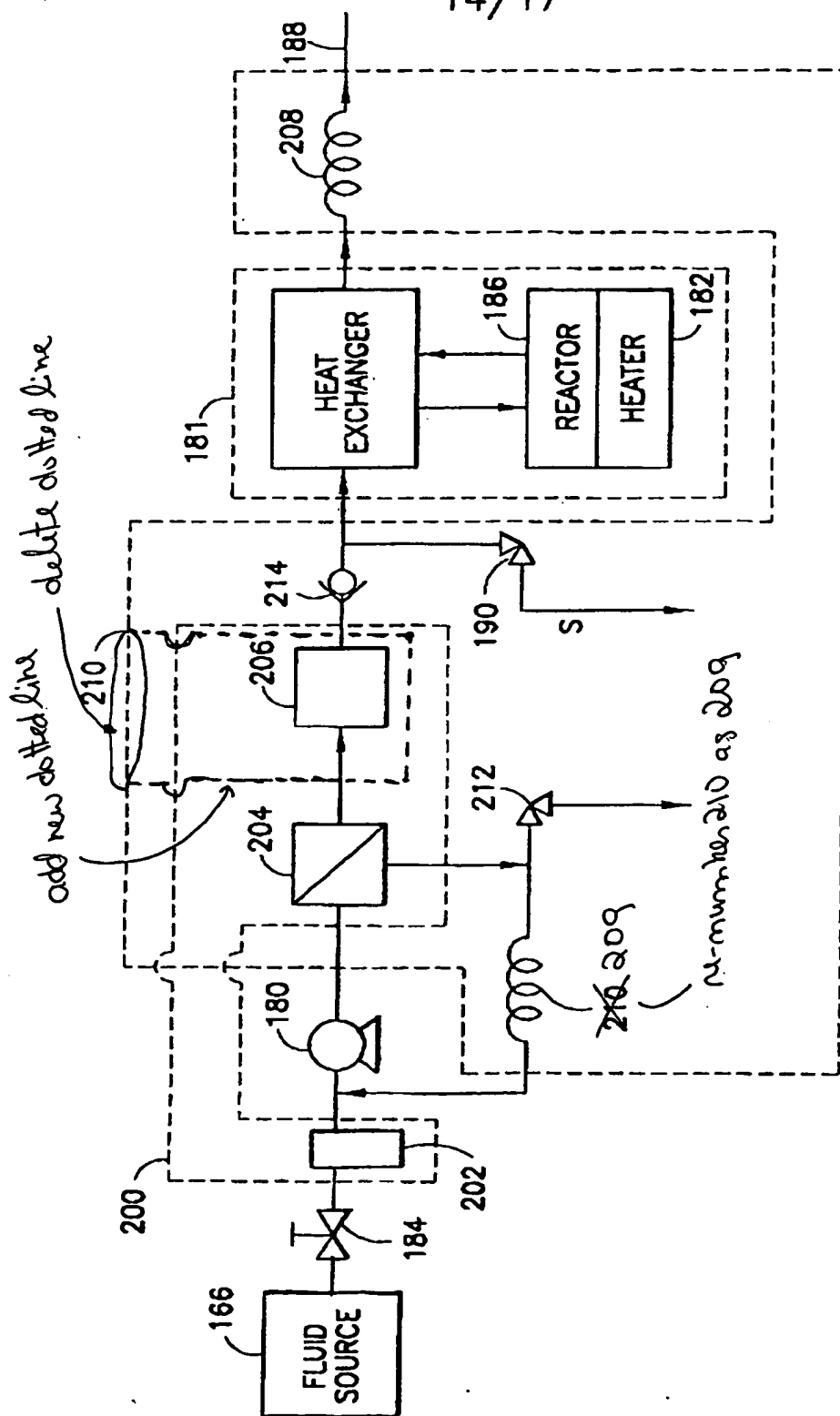


FIG.11A

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# REPLACEMENT SHEET

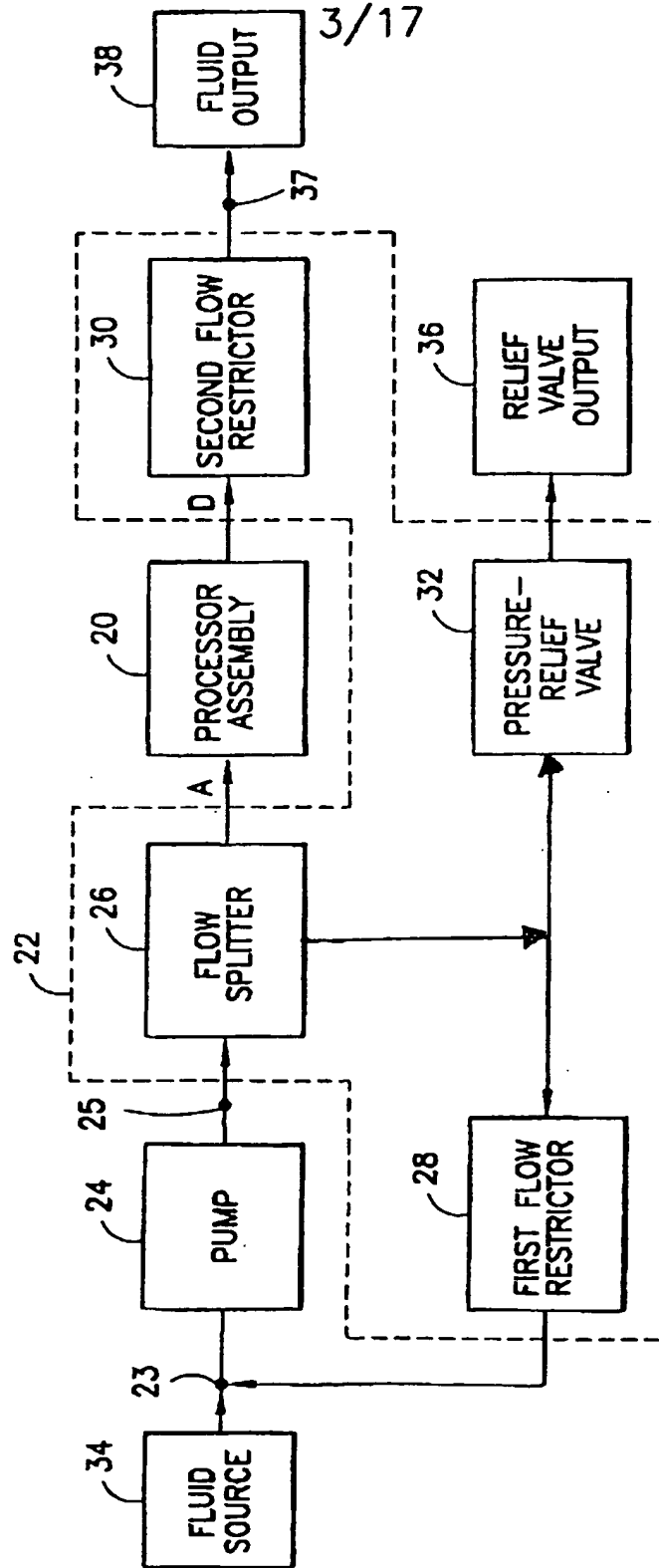


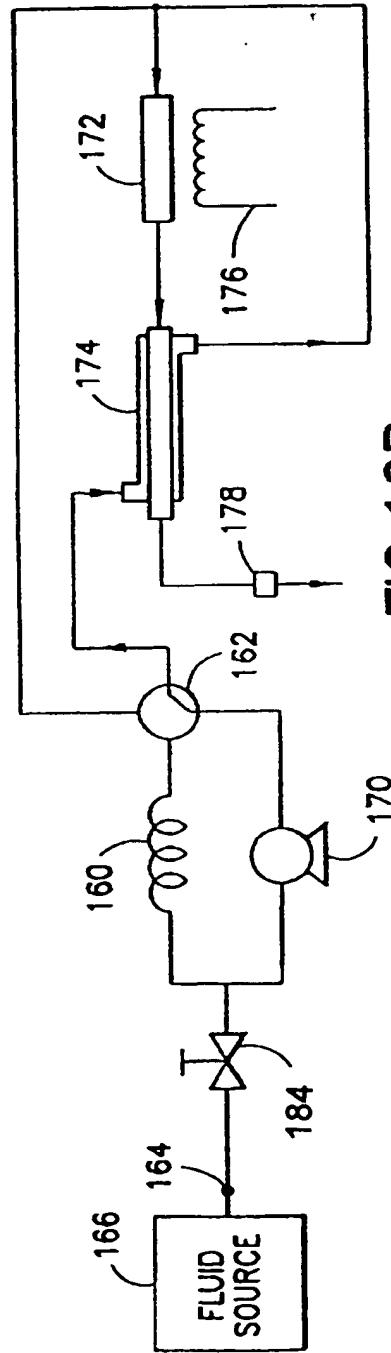
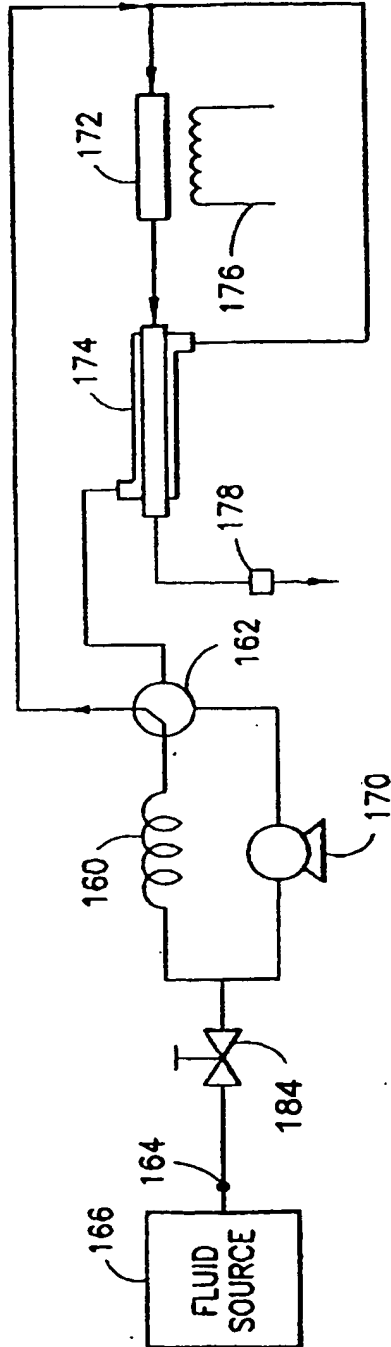
FIG.3

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148

# REPLACEMENT SHEET

13/17

## PROCESSOR ASSEMBLY



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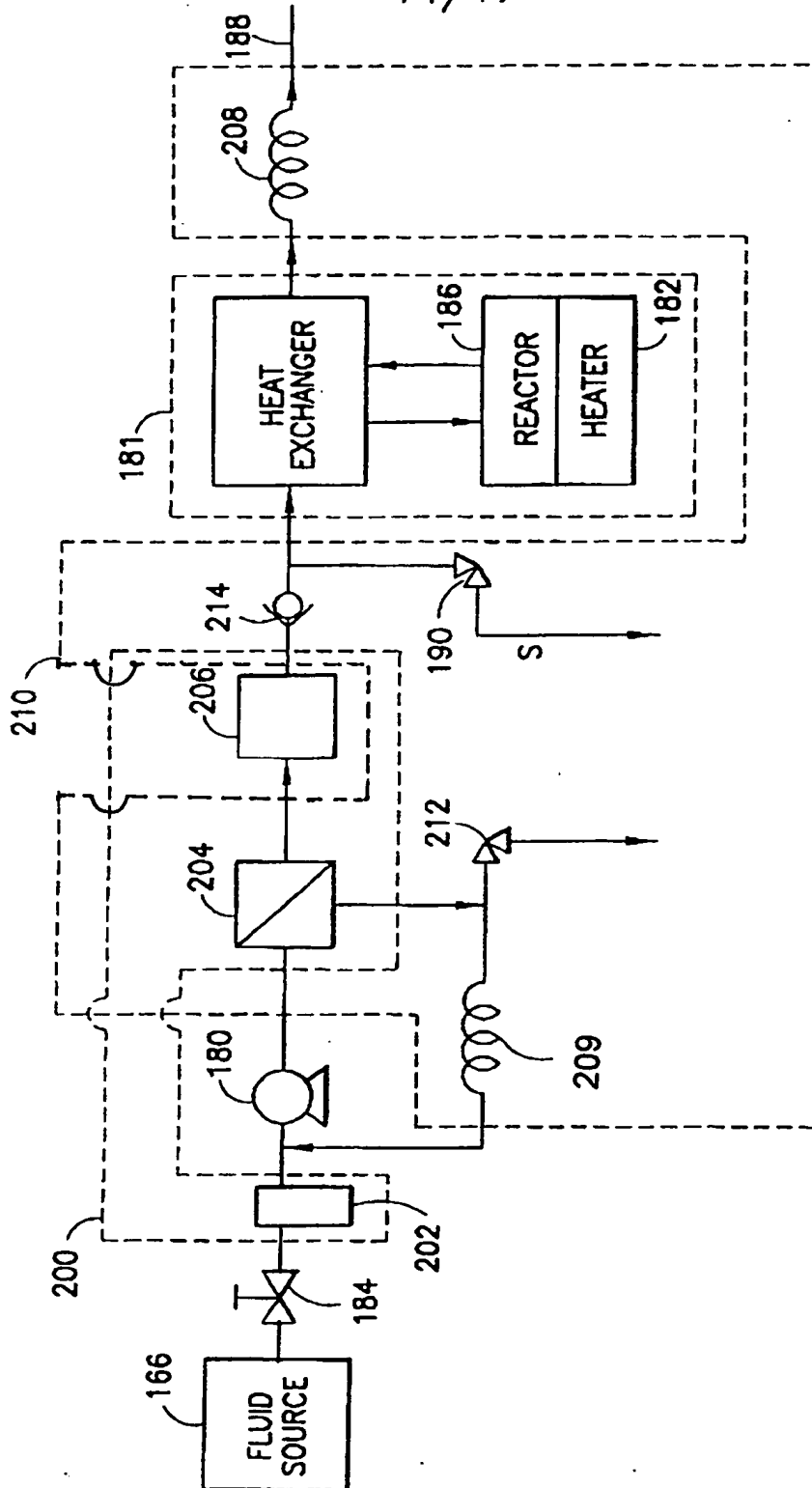


FIG. 11A *Okay to install.*  
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